Dosing Patterns and Early Safety and Effectiveness Outcomes in Patients with Multiple Myeloma Treated with Teclistamab in the Community Setting

Timothy Beer¹; Gloria Graf²; Dee Lin³; Mariana Fernandez⁴; Margaret Doyle⁵; Laura Hester⁶; Bingcao Wu³; Stephen Huo²

¹ Ann B. Barshinger Cancer Institute, Penn Medicine Lancaster General Health
 ² Janssen Global Services, LLC, Raritan, NJ, USA
 ³ Janssen Scientific Affairs, LLC, Horsham, PA, USA
 ⁴ Janssen-Cilag SA, Madrid, Spain
 ⁵ Janssen Sciences Ireland, Dublin, Ireland
 ⁶ Janssen Research & Development, LLC, Raritan, NJ, USA

https://www.congresshub.com/ASH2024/ Oncology/Teclistamab/Beer

The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.



Presented by G Graf at American Society of Hematology; December 7, 2024; San Diego, CA, USA

Background

- Teclistamab (Tec) is the first B-cell maturation antigen (BCMA) x CD3 bispecific therapy for relapsed/refractory multiple myeloma (MM), with weight-based dosing and the longest study follow-up of any bispecific antibody in MM¹
- Following US regulatory approval in October 2022, Tec step-up dosing (SUD) has been initiated primarily in academic medical centers on an in-patient basis. As physicians gain real-world experience with teclistamab, expansion of treatment initiation to community practices represents an important means to improve access to more patients
- More data are needed to evaluate feasibility, in-patient/out-patient administration models during the SUD period, and patient outcomes associated with community-based teclistamab administration
- This study characterized teclistamab step-up and continuous dosing patterns, and early clinical/safety outcomes in a real-world cohort of MM patients treated in community practices



Methods

- Data source
 - Integra Connect is a linked EHR/claims database of >50 community-based oncology networks across the United States, representing 6000+ providers across 900+ sites of care
- Population
 - Adult patients with MM who received at least one treatment dose (1.5 mg/kg) of teclistamab after October 25, 2022 (FDA approval date) and before April 1, 2024 (last data availability)
 - Subgroup of patients who completed SUD in the community setting was also identified
- Analysis
 - Demographics, clinical characteristics, dosing patterns, and safety outcomes were reported descriptively.
 - Duration of therapy (DoT) and time to less frequent dosing (Q2W or less often) were reported using the Kaplan-Meier estimator. To standardize measurement of follow-up time, the primary index date for TTE outcomes was set to the date of the first observed full Tec dose
 - CRS incidence and severity were identified using ICD-10 codes linked to the patient record during the SUD period



Study Population

- 108 patients with MM who received at least one treatment dose of teclistamab in the community setting were identified (table, right)
- A subset of 25 patients (23%) was identified as having completed the entire SUD process in a community practice, almost exclusively (98%) in the inpatient setting
 - Four patients (4%) with incomplete evidence of community-based SUD were also identified

Base	line d	chara	cteristics
	_		

J'S	Overall (N=108)	Community SUD subsample (N=25)
Age (years), median (range)	64.5 [37, 85]	61.0 [37, 83]
Male, n (%)	65 (60%)	14 (56%)
Race	n=77	n=9
White, n (%)	66 (86%)	5 (56%)
Black/African American, n (%)	10 (13%)	3 (33%)
Asian, n (%)	1 (1%)	1 (11%)
Ethnicity	n=99	n=25
Hispanic or Latino, n (%)	7 (7%)	6 (24%)
Not Hispanic or Latino, n (%)	92 (93%)	19 (76%)
Payer Type at Baseline	n=76	n=13
Commercial, n (%)	21 (28%)	5 (38%)
Medicare/Medicaid, n (%)	53 (70%)	8 (62%)
Self Pay, n (%)	2 (2%)	0 (0%)
BCMA exposure at any time prior to index, n (%)	21 (19%)	8 (32%)
Triple-class ^a exposed, any time prior to index, n (%)	98 (91%)	22 (88%)
Penta-drug ^b exposed, any time prior to index, n (%)	49 (45%)	13 (52%)
Median follow-up time, months [range]	5.0 [0.2, 15.0]	5.0 [0.6, 14.7]

Note: Missing values were excluded from percentage calculations; denominators for categorical variables are indicated in above table using italicized text $a \ge 1 \text{ PI}, \ge 1 \text{ IMiD}, 1 \text{ anti-CD38 mAb}.$ $b \ge 2 \text{ PIs}, \ge 2 \text{ IMiDs}, 1 \text{ anti-CD38 mAb}$

Step-Up and Maintenance Dosing Schedules

- Among patients who completed SUD in the community setting, 92% (n=23) followed a per-label step-up dosing schedule (figure, right)
- Of the 108 patients who received at least one treatment dose of teclistamab in the community setting, 94% started with the labeled QW schedule; 36% transitioned to Q2W or less frequent dosing (outside of label) over the course of follow-up; 87% of transitions were to a Q2W schedule
- Median time to change of dosing schedule was 5.5 months from the first treatment dose

Step-Up Dosing Schedule, among patients completing SUD in the community setting (n=25)

6

10

Days 1, 3, 5
Days 1, 4, 6
Days 1, 4, 7
Days 1, 5, 7
Days 1, 5, 8
Days 1, 6, 9
Days 1, 7, 10



Early Safety and Effectiveness Outcomes

Safety outcomes during SUD period

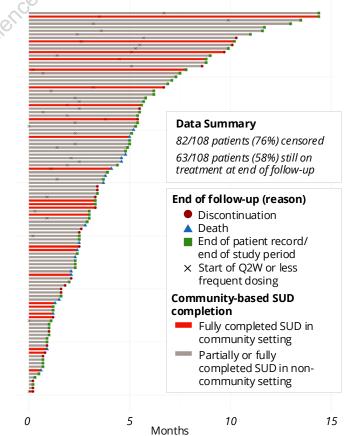
- 32% (8/25) of patients who completed SUD in the community setting (98% in-patient) had at least one record of CRS occurrence during the SUD period
- All CRS events were either Grade 1 or Grade 2
- Median time to first CRS onset was 4 days

Early effectiveness outcomes

- At 5 months median follow-up, 24% of all patients had discontinued treatment. K-M median duration of treatment was 10.3 months; reason for discontinuation was not captured in the data (figure, right)
- Median OS was not reached

FIGURE 3. Duration of therapy (DoT), months

The figure shows duration of therapy for 108 patients who received at least one full dose of Tec in the community setting. Over study follow-up, 24% of patients discontinued Tec and 76% were censored; the high proportion of censoring observed reflects the limited (median 5.5 months) follow-up time of this study.





Conclusions and Key Takeaway

- Patients initiated and treated with teclistamab in a community-based setting, primarily with in-patient step-up dosing administration, had comparable safety profiles to those treated in academic medical centers (previously reported)^{2,3}
- Early results from community-based teclistamab administration appeared promising in terms of feasibility, adherence to PI-recommended SUD schedules, and early clinical outcomes
- Teclistamab administration in the community setting is feasible and an important opportunity to improve access to more patients with RRMM

² Pianko et al. (2024, June 13-16). Real-World Schedule De-escalation of Teclistamab In Patients with Relapsed Or Refractory Multiple Myeloma – A US National Healthcare Claims Analysis [Conference Poster]. European Hematology Association, Madrid, Spain.

³ Banerjee et al. (2024, June 13-16). Teclistamab (Tec) Step-Up Dosing (SUD) And Treatment Dose Schedule De-escalation in the Real-World (RW) Setting – An Analysis of Multicenter Electronic Medical Records [Conference Poster]. European Hematology Association, Madrid, Spain.





motionalus

https://www.congresshub.com/ASH2024/ Oncology/Teclistamab/Beer

The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.